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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/691,374	10/22/2003	Claire M. McCallum	02,276-A	2394	
759	7590 04/07/2005			EXAMINER	
Alison J. Baldwin			SAMSON, MARIA TERESA D		
McDonnell Boehnen Hulbert & Berghoff 32nd Floor			ART UNIT	PAPER NUMBER	
300 S. Wacker Drive			1638		
Chicago, IL 60	606		DATE MAILED: 04/07/2005		

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
·	10/691,374	MCCALLUM ET AL.			
Office Action Summary	Examiner	Art Unit			
	Maria Teresa Samson	1638			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
 1) Responsive to communication(s) filed on 31 January 2005. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. 					
Disposition of Claims					
 4) Claim(s) 1-34 is/are pending in the application. 4a) Of the above claim(s) 1-11, 18, 19 and 25-34 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 12-17 and 20-24 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 					
Application Papers					
9) The specification is objected to by the Examiner.					
10)⊠ The drawing(s) filed on <u>22-October 2003</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 15-March 2004. 15 Retent and Trademark Office. 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. 5) Notice of Informal Patent Application (PTO-152) 6) Other: See search note.					

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DETAILED ACTION

Applicant's election without traverse of Group II, claims, 12-17 and 20-24, and SEQ ID NO: 1 in the reply filed on 31 January 2005 is acknowledged.

Claims 1-34 are pending.

Claims 12-17 and 20-24 are examined on the merits.

Specification

(A.) If applicant desires priority under 35 U.S.C. 111(a) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ______" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after

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November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

- (B.) The specification is objected to because on page 28, line 10, "former" is misspelled.
- (C.) The specification is objected to because it is not clear if the applicant is referring to mutation 13345 on page 28, line 9. I assume that the applicant is referring to mutation 13342 since the tomato plant that exhibits lower activity of PG is described under the heading "Identification and evaluation of mutation 13342".

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(D.) Figures 4-9 are objected to because the figures cannot have a brief description on the legend of the figure.

(E.) Figures 1-3 are objected to because the figures do not corresponds to the legends of the figures.

Claim Objections

Claim 12 is objected to because of the following informalities:

In claim 12, "SEQ. ID. No.1" should be replaced with, --SEQ ID NO:1--.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(A.) Claims 12-17 and 20-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to any fruit endogenous polygalacturonase gene having a mutation within the endogenous fruit polygalacturonase gene that is substantially homologous to SEQ ID NO: 1, a tomato fruit comprising an endogenous polygalacturonase gene having a mutation that occurs around nucleotide 1969 of SEQ ID NO: 1 and this mutation results in a change in at least amino acid 178 of the PG and a tomato fruit comprising an endogenous polygalacturonase gene having

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a mutation that occurs around nucleotide 2940 of SEQ ID NO: 1 and this mutation results in a change in at least amino acid 252 of the PG polypeptide.

Applicant does not describe any endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation within the endogenous fruit polygalacturonase gene, an endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation that occurs around nucleotide 1969, an endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation that creates a change in at least amino acid 178 of the fruit polygalacturonase enzyme, an endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation that occurs around nucleotide 2940, and fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation that creates a change in at least amino acid 252 of the fruit polygalacturonase enzyme which lead to a reduction in the activity of PG.

Furthermore, there is no functional description of an endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation within the endogenous fruit polygalacturonase gene that results in a reduction in the activity of PG. Applicant does not describe the sufficient structural elements of SEQ ID NO: 1 that are required for function and that these structural elements are also present in an endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1. The Applicant does not describe the sufficient structural elements of a representative number of nucleic acids that is substantial homologous to SEQID NO: 1 and a change in a nucleic acid which is part of the structural elements that can lead to the reduction in the activity of PG.

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Hence, the specification fails to provide an adequate written description of the genus claimed.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed nucleic acids, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

(B.) Claims 12-17 and 20-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a tomato fruit comprising an endogenous polygalacturonase gene having a mutation that is associated with a G to A change at nucleotide 1969 of SEQ ID NO: 1 and this mutation results in a change from glycine to arginine at amino acid 178 of the PG and said tomato fruits containing the mutation 13345 exhibit lower PG enzyme activity compared to their wild type sibling, and are considered firmer than the wild type sibling, a tomato fruit comprising an endogenous polygalacturonase gene having a mutation that is associated with a T to A change at nucleotide 2940 of SEQ ID NO: 1 and this mutation results in a change from histidine to glutamine at amino acid 252 of the PG polypeptide and said tomato fruits containing the mutation 13342 exhibit lower PG enzyme activity compared to their wild type sibling and are considered firmer than the wild type sibling does not reasonably provide enablement for any endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation within the endogenous fruit polygalacturonase gene, an endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation that occurs around nucleotide 1969, a tomato plant, tomato fruits, seeds, pollen, plant parts, and progeny of the

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tomato plant, food and food products incorporating the fruit of the tomato plant containing the endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation that occurs around nucleotide 1969, an endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a nontransgenic mutation that creates a change in at least amino acid 178 of the fruit polygalacturonase enzyme expressed from the fruit polygalacturonase gene, an endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a nontransgenic mutation that occurs around nucleotide 2940, a tomato plant, tomato fruits, seeds, pollen, plant parts, and progeny of the tomato plant, food and food products incorporating the fruit of the tomato plant containing the endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation that occurs around nucleotide 2940, an endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation that creates a change in at least amino acid 252 of the fruit polygalacturonase enzyme expressed from the fruit polygalacturonase gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to any fruit endogenous polygalacturonase gene having a mutation within the endogenous fruit polygalacturonase gene that is substantially homologous to SEQ ID NO: 1, a tomato fruit comprising an endogenous polygalacturonase gene having a mutation that occurs around nucleotide 1969 of SEQ ID NO: 1 and this mutation results in a change in at least amino acid 178 of the PG and a tomato fruit comprising an endogenous polygalacturonase gene

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having a mutation that occurs around nucleotide 2940 of SEQ ID NO: 1 and this mutation results in a change in at least amino acid 252 of the PG polypeptide.

Applicant's teachings only provide guidance for mutagenesis of tomato seeds of cultivars Shady Lady (hybrid) and NC 84173 (page 18, example 1); extraction and preparation of DNA from the M2 plants (example 1, page 19); tilling (example 1, page 20); physical and biochemical measurements: squeeze test, color determination, assays for PG activity, DNS based assay for PG activity, BCA based assay for PG activity, western blot (example 1, pages 22-26).

Applicant teaches tomato fruits containing the mutation 13345 which exhibit reduced PG enzyme activity compared to their wild type sibling, and are considered firmer than the wild type sibling (page 27). Sequence analysis shows that the mutation is associated with a G to A change at nucleotide 1969 of SEQ ID NO: 1, counting A in the ATG of the start codin as nucleotide position 1. This mutation results in a change from glycine to arginine at amino acid 178 of the PG polypeptide.

Applicant further teaches tomato fruits containing the mutation 13342 (recites 13345?) which exhibit reduced PG enzyme activity compared to their wild type sibling, and are considered firmer than the wild type sibling (page 28). Sequence analysis shows that the mutation is associated with a T to A change at nucleotide 2940 of SEQ ID NO: 1, counting A in the ATG of the start codon as nucleotide position 1. This mutation results in a change from histidine to glutamine at amino acid 252 of the PG polypeptide.

The specification does not teach making any endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation within the endogenous fruit polygalacturonase gene, an endogenous fruit polygalacturonase gene that is

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substantial homologous to SEQID NO: 1 and having a non-transgenic mutation that occurs around nucleotide 1969, an endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation that creates a change in at least amino acid 178 of the fruit polygalacturonase enzyme, an endogenous fruit polygalacturonase gene that is substantial homologous to SEQID NO: 1 and having a non-transgenic mutation that occurs around nucleotide 2940, and having a non-transgenic mutation that creates a change in at least amino acid 252 of the fruit polygalacturonase enzyme which lead to a reduction in the activity of PG. The specification does not exemplify a tomato fruit having a mutation either around nucleotide 1969 or around nucleotide 2940 within the endogenous PG gene and the mutation results in a change in at least amino acid 178 of the PG enzyme or in a change in at least amino acid 252 of the PG enzyme that leads to a reduction in the activity of PG much less any gene having a mutation within the fruit endogenous PG gene with the full scope of the claims and does not teach to make them.

It is well known to those skilled in the art that making substitutions in a nucleic acid does not produce predictable results. Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252) showed that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Similarly, Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those

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histidines with the "conservative" amino acid arginine drastically reduced enzyme activity (see Table 1).

In addition, the specification does not provide any guidance with regard to what structural features are required for activity of PG that when alter can reduced the activity of PG, and the claims are drawn to a multitude of sequences. The specification does not discuss conserved residues between the claimed sequence and known sequences from other fruits identified as PG that might be important for PG's activity. On page 17, line 15, the applicant recites that G178 is one of the fifteen most conserved residues within the glycoside hydrolase protein family. Also, on page 18, line 1, the applicant recites that the H252Q mutation is within block D of the glycoside hydrolase protein family and is a change in a very conserved region of this protein.

The applicant does not describe the other conserved regions of PG and conserved residues within block D or within the glycoside hydrolase protein family that are important for the activity of PG.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids encoding proteins with 99.8% identity to SEQ ID NO: 2. Making all possible single amino acid substitutions in a 457 amino acid long protein like that encoded by SEQ ID NO: 2 would require making and analyzing 19⁴⁵⁷ nucleic acids; these proteins would have 99.8% identity to SEQ ID NO: 2. Because nucleic acids encoding proteins with 99.8% identity to SEQ ID NO: 2 would encode proteins with many amino acid substitutions, many more than 19⁴⁵⁷ nucleic acids would need to be made and analyzed. Guo et al. (2004, Proc. Natl. Acad. Sci. USA 101: 9205-9210) teach that while proteins are fairly tolerant to mutations resulting in single

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amino acid changes, increasing the number of substitutions additively increases the probability that the protein will be inactivated (pg 9209, right column, paragraph 2). Thus, making and analyzing proteins with many amino acid substitutions that also have PG activity would require undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-17 and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claim is included in all rejections.

(A.) The term "having substantial homology" in claim 12 is a relative term which renders the claim indefinite. The term "having substantial homology" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-17 and 20-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is drawn to an endogenous fruit polygalacturonase gene that is substantially homologous to SEQ ID NO: 1 and possesses a mutation within the gene, which is a product of nature. Also, in claims 15 and 22, the tomato

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fruits, seeds pollen, plant parts and the progeny of the tomato plant comprising the polygalacturonase gene having a mutation within the gene may not retain the mutation. Thus is a product of nature.

Claims 12-17 and 20-24, as written, does not sufficiently distinguish over nucleic acids as they exist in nature because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested that the claims are modified to refer to the hand of the inventor, *e.g.* by replacing "the" in claims 12-14, 17, 20 and 24 with –an isolated--. In addition, claims 15 and 22 should be amended to make clear that the progeny comprise the polygalacturonase gene of the earlier claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (A.) Claim 12 is rejected under 35 U.S.C. 102 (b) as being anticipated by Atkinson et al (Plant Physiol., 103:669-670, 1993). Atkinson et al teach an endogenous fruit polygalacturonase gene having substantial homology to SEQ ID NO: 1 because it has 54.6% similarity to it (see

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search result) and having a non-transgenic mutation within the endogenous fruit polygalacturonase gene.

Claim Rejections - 35 USC § 102/103

(A.) Claims 12, 15, 16, 22 and 23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brummell et al (Brummell et al., Plant Molecular Biology, 47:311-340, 2001).

Claims 12, 15, 16, 22 and 23 require that a tomato plant, tomato fruits, seeds, pollen, plant parts, progeny of the tomato plant, food and food products incorporating the fruit of the tomato plant comprising the endogenous fruit polygalacturonase gene that is substantially homologous to SEQ ID NO: 1 and has a mutation that leads to a reduction in the activity of PG. Hence, integrity of stored tomato and the textural properties of the paste are improved by a reduction in the activity of PG.

Brummell et al teach that the suppression of PG results in the improvement in the integrity of stored tomato fruit and the textural properties of the tomato paste (page 318, column 1, second paragraph).

Brummell et al teach that the suppression of PG results in the improvement in the integrity of stored tomato fruit and the textural properties of the tomato paste as claimed in the instant application. The examiner is unable to determine what the properties of the product are since not enough information is given to know what the differences are between the product of the instant application and the product describes by Brummell et al and if there are any differences.

The USPTO/examiner is not in a position to make either a conclusion of "inherency/anticipation" or "obviousness" since the record does not allow one to determine if

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and how the claimed subject matter differs from the prior art. Accordingly, the burden shifts to applicant to provide evidience that the prior art would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Teresa Samson whose telephone number is 571-272-3110. The examiner can normally be reached on 7:00-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Maria Teresa Samson, Ph.D March 28, 2005 ELIZABETH MICELWAIN
PRIMARY EXAMINER